CLAIMS

We claim:

1. A substantially moisture stable pharmaceutical preparation in the form of a solid oral dose comprising;

(c) an active core comprising a granulated pharmaceutically active ingredient; and

(d) a moisture barrier coating enveloping individual granules of the active core.

2. A pharmaceutical preparation as claimed in claim 1, wherein the moisture barrier coating permeates the active core, enveloping individual granules of the core.

3. A pharmaceutical composition according to claim 2, wherein granules in the region of the center of the active core are surrounded with and contacted by the moisture barrier coating.

4. A pharmaceutical preparation as claimed in claim any preceding claim, wherein the active pharmaceutical ingredient is paroxetine hydrochloride anhydrate or paroxetine hydrochloride hemihydrate.

5. A pharmaceutical preparation as claimed in any preceding claim, wherein the barrier coating is hydrophobic.

6. A pharmaceutical preparation as claimed in any preceding claim, wherein the barrier coating further comprises a nonionic surfactant.

7. A pharmaceutical preparation as claimed in any preceding claim, wherein the barrier coating comprises a moisture barrier agent selected from one or more of the following agents: ethyl cellulose, polyethylene glycols, polyglycolised glycerides, fatty alcohols, stearic acid, opadry AMB OY-B-28920 white and Opadry 20A 58900 white and fatty materials of plant and animal origin.

8. A pharmaceutical preparation as claimed in any preceding claim, incorporating anhydrous citric acid for pH related stability adjustment.

9. A pharmaceutical preparation as claimed in any preceding claim, further comprising one or more of the following ingredients: a diluent, a disintegrant and a lubricant.

10. A pharmaceutical preparation as claimed in claim 9, wherein dibasic calcium phosphate or microcrystalline cellulose is used as a diluent.

11. A pharmaceutical preparation as claimed in any one of claims 8 to 10, wherein sodium starch glycollate is used as a disintegrant.

12. A pharmaceutical preparation as claimed in any of claims 8 to 11, wherein magnesium stearate is used as a lubricant.

13. A pharmaceutical preparation as claimed in preceding claim, wherein the preparation is in the form of a tablet or the preparation is placed within a capsule.

14. A pharmaceutical preparation as claimed in claim 13, wherein the tablet is caplet shaped.

15. A pharmaceutical preparation as claimed claim 13 or claim 14, wherein the granules are compressed into tablets with hardness ranging from 150- 200 Norton

16. A pharmaceutical preparation as claimed in any of claims 13 to 15, wherein the tablets are optionally further coated with conventional film coating materials.

17. A pharmaceutical preparation as claimed claim 16, wherein the film coating is a hydrophobic material.

18. A pharmaceutical preparation as claimed in any preceding claim, wherein the pharmaceutical preparation is substantially resistant to moisture-degradation of the active ingredient and/or the development of pink hue.

19. A pharmaceutical preparation as claimed in any preceding claim, wherein the pharmaceutical preparation further comprises pharmaceutically acceptable excipients in order to mask the taste of the preparation.

20. A pharmaceutical preparation as claimed in any of claims 11 to 12 and 17 to 18, wherein the preparation is placed into hard gelatin capsules

21. A process for producing a substantially moisture stable pharmaceutical preparation in the form of a solid oral dose as described in any one of claims 1 to 19 comprising the steps of:

(d) granulated a pharmaceutically active ingredient to form a granulated active core;

(e) coating the individual granules of the active core with a barrier coating comprising a moisture barrier agent; and

(f) forming the coated granules into a solid oral dose.

22. A process according to claim 21, wherein the coating is achieved by contacting individual granules of the active core with a solution of the moisture barrier agent in an organic solvent.

23. A procees according to claim 22, wherein the contacted granules are dried to remove the organic solvent and provide individual coated granules.

24. A process according to claim 22 or claim 23 wherein the organic solvent is selected from methylene chloride, isopropyl alcohol, acetone and mixtures of one or more thereof.

25. A process according to claim 24, wherein Polysorbate 80 is added to the organic solvent.